

# ***Inspection Procedures for Compliance Monitoring of the Biological Weapons Convention***

**Jonathan B. Tucker, Editor**

Proceedings of a workshop held in Livermore, California  
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**Center for Global Security Research**



**Lawrence Livermore National Laboratory  
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# Inspection Procedures for Compliance Monitoring of the Biological Weapons Convention

## Summary of Workshop Discussion

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### Disclaimer

*The following Summary of Discussion does not necessarily reflect the official views of the U.S., Canadian, or British governments nor of the U.S. pharmaceutical industry, nor should it imply endorsement by the workshop participants of any of the ideas or opinions expressed below.*

### Introduction

The 1972 Biological and Toxin Weapons Convention (BWC) prohibits the development, production, stockpiling, and transfer of biological weapon (BW) agents in types and quantities beyond those justifiable for defensive or other peaceful purposes. Although the BWC lacks verification provisions, several events in recent years have indicated that mechanisms for assessing compliance are needed. These events include the revelation that one of the depository countries—the Soviet Union, later Russia—maintained an active BW program in violation of the convention until 1992 and may still be in violation; the finding by the United Nations Special Commission that Iraq had produced and stockpiled biological munitions prior to the 1991 Persian Gulf War; and information indicating that several other countries are pursuing BW capabilities.

With these considerations in mind, BWC states parties, meeting at a special conference in Geneva in September 1994, established an Ad Hoc Group with the mandate to “consider appropriate measures, including possible verification measures” that would be specified in a legally binding protocol to the BWC. Since early 1995, the Ad Hoc Group has met periodically in Geneva to discuss these issues. At the urging of the Fourth Review Conference of the BWC in late 1996, the Group at its July 1997 meeting began to consider draft language for a BWC protocol in the form of a “rolling text.” Among the elements being considered for inclusion in the protocol is an integrated set of measures for monitoring BWC compliance, including on-site inspections of relevant biological facilities and field investigations of alleged BW use and suspicious outbreaks of disease.

The challenge facing the Ad Hoc Group is to craft a workable compliance regime that enhances deterrence and confidence while minimizing any adverse consequences for industrial competitiveness and national security. To help illuminate the complex issues and tradeoffs involved in crafting a compliance protocol for the BWC, the Center for Nonproliferation Studies at the Monterey Institute of International Studies and the Center for Global Security Research at Lawrence Livermore National

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Laboratory cosponsored a workshop on *Inspection Procedures for Compliance Monitoring of the Biological Weapons Convention (BWC)* in Livermore, California, on May 29–30, 1997. This workshop was the sequel to a workshop on the utility of sampling and analysis for BWC compliance monitoring, held in Washington, D.C. on October 7–8, 1996.<sup>1</sup>

Attending the Livermore workshop were some 30 experts from the U.S., British, and Canadian governments, the national laboratories, the U.S. pharmaceutical industry, nongovernmental organizations, and academia. (See Appendix B: List of Workshop Participants.) The first day of the workshop focused on facility inspections and the second day on field investigations of alleged BW use and unusual outbreaks of disease. To promote a frank and open exchange of views, all discussion was conducted on a not-for-attribution basis. The following summary covers the key points made during the workshop. Appendix A contains the keynote address given at the workshop by Ambassador James F. Leonard, who headed the U.S. delegation to the BWC negotiations in Geneva in the early 1970s.

### Objectives of a Compliance Regime

Considerable differences existed among workshop participants in their estimates of the net deterrence and confidence-building value of adding inspections to a BWC compliance regime. Several participants stated that on-site inspections could increase confidence in the BWC by enhancing transparency and reducing ambiguities about compliance, and could help deter violations

by increasing the probability of detection. But others noted that even with new monitoring technologies being developed, the chances of detecting a violation would be low and the regime could risk creating false confidence. Furthermore, on-site inspections would impose costs on the pharmaceutical and biotechnology industries, whose facilities would be potentially subject to inspection, and could jeopardize confidential proprietary information (CPI) and national-security information unrelated to the convention.

Nevertheless, various participants raised the following objectives for a BWC compliance regime:

- In conjunction with other policy instruments, to help prevent the acquisition and use of biological weapons, although the ultimate approach may differ from that of the Chemical Weapons Convention (CWC), which entered into force in April 1997;
- To reinforce the international norm against BW acquisition and use;
- To build confidence in the compliance of states parties through greater openness and transparency with respect to biological defense programs and dual-capable biological facilities;
- To help deter violations of the BWC, recognizing that confidence in the ability of the regime to detect all significant violations may be low;
- To create a framework for confirming and acting on intelligence information obtained primarily through national means;
- To establish a process that will apply pressure on BW proliferators by uncovering and observing suspicious sites, recognizing that this process may take a long time and may never produce a “smoking gun”;
- Through cooperative activities under Article X, to inform biological scientists throughout the world

<sup>1</sup> Jonathan B. Tucker (ed.), *The Utility of Sampling and Analysis for Compliance Monitoring of the Biological Weapons Convention: Proceedings of a Workshop Held in Washington, D.C., October 7–8, 1996* (Livermore, CA: Lawrence Livermore National Laboratory, Report No. CGSR-97-001, February 1997).



- about the BWC and promote responsible behavior, while enhancing public safety and international health;
- Ultimately, to help create conditions that would compel all states to comply with international norms, so that assurance gradually replaces deterrence.

### Desirable Level of Intrusiveness

Multilateral disarmament treaties inevitably entail some “pain” in that all parties must be prepared to accept the same monitoring measures they wish to impose on others. Such reciprocity may require asking pharmaceutical and biotechnology companies in the industrialized countries to bear significant near-term economic costs in return for a future security payoff that is difficult to quantify. Indeed, U.S. industry worries that the industrialized countries, where the problem of noncompliance is presumably lower, may end up bearing most of the inspection burden.

Some workshop participants argued that the United States should be realistic about the level of intrusiveness it pursues in Geneva and avoid measures that put valuable industry and national-security information at risk without providing substantial benefits in terms of treaty compliance. Other participants expressed greater confidence in the value of inspections and responded that an overly watered-down regime would be ineffective as a deterrent. They argued that while the BWC is not verifiable to the same standard as other disarmament treaties, in the sense that one is unlikely to find clear-cut evidence of a violation, it is still possible to set up a system whereby BW proliferators can be “ground down” by being forced to justify their activities to the international community.

Since noncompliance with the BWC might involve a spectrum of activities ranging from development of BW agents to

large-scale production and use, the effectiveness of various monitoring measures will be somewhat scenario-dependent. Thus, rather than focusing on individual facilities, it is important to consider a state party’s record as a whole, including the accuracy of its declarations and the presence of anomalies at multiple sites. The investigation of Iraq’s BW program by the United Nations Special Commission (UNSCOM) has shown that even without finding a “smoking gun,” on-site inspections can provide indicators of falsehoods and inconsistencies in official declarations and statements. UNSCOM’s experience has also demonstrated that because evidence from various sources accumulates slowly, assessing a country’s BW capability may require persistent detective work over a period of years.

States parties with substantial intelligence-gathering capabilities, such as the United States, may wish to rely primarily on national means of intelligence collection to determine which countries are cheating, and then use the international regime to shine a spotlight on violators and attempt to expose them. However, a number of countries—including some suspected of developing biological weapons—want to exclude nationally collected intelligence as a basis for requesting challenge inspections on the grounds that such information is “discriminatory” because only the advanced industrialized countries have access to sophisticated collection technologies.

### Transparency and the Internet

Participants agreed that a BWC compliance regime should promote transparency without imposing an undue burden on industry. One approach would be to reinforce the norm against BW acquisition and use through nontraditional means, such as using the Internet to facilitate the exchange of information on unusual outbreaks of

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disease. A large amount of epidemiological information is already available on the World Wide Web, including the epidemiology news services maintained by the Program on Monitoring Emerging Diseases (ProMED), the U.S. Centers for Disease Control and Prevention (CDC), and the World Health Organization (WHO). While promoting the exchange of epidemiological data is not a panacea, it is cost-effective, may drive positive cultural change, and would make it harder for governments to control the flow of treaty-relevant information. An informal global network for exchanging epidemiological information would also help educate biologists about the BWC and reinforce the international norm against biological warfare, since many scientists in countries of proliferation concern may be unaware of the convention.

Other participants raised the objection that an informal exchange of information among scientists would do little to reinforce the norm of nonacquisition and nonuse of biological weapons by *governments*, which is the most important objective. For example, despite the remarkable expansion of contacts and communications between Russian and Western scientists in recent years, the Russian government has still not resolved certain BWC compliance concerns raised by the United States and other countries. Whether or not an individual scientist is aware of the BWC, if his government orders him to make biological weapons, he will probably do so. Thus, the primary objective of the BWC compliance regime should be to influence government behavior. Most workshop participants agreed that while the exchange of data through the Internet could enhance transparency, it should not be the primary basis of the BWC compliance protocol.

### Evidence for Judging Noncompliance

What type of evidence is needed to persuade the international community that a

BWC violation has occurred or is not occurring? Consider the criminal and civil trials of O.J. Simpson. The defense won the criminal case against Simpson, which required the jury to find him guilty “beyond a reasonable doubt,” but lost the civil case, which required the jury to find a “preponderance of evidence” for his guilt. Thus, the two verdicts were apparently based on different standards of evidence. The various proposed objectives for the BWC compliance regime also imply different levels of proof. Is the purpose of the compliance protocol to impose punitive sanctions on violators, which would require a high standard of proof, or simply to heighten awareness that the activities of a particular country are suspicious?

In the past, the United States has tried to orchestrate sanctions against suspected BW proliferators but has been unable to mobilize the international community. During the 1979 outbreak of human anthrax in the Soviet city of Sverdlovsk, the U.S. government linked the epidemic to an accident at a Soviet military facility, yet many countries (as well as a few U.S. scientists) were not persuaded. The same was true of the “yellow rain” controversy of the early 1980s, when the U.S. government released what it believed was compelling evidence that the Soviet Union was assisting its Laotian and Vietnamese communist allies in employing chemical weapons and mycotoxins against internal resistance forces and civilians in Laos and Cambodia.

What types of evidence are needed to persuade the international community that a BWC violation has occurred? One problem is that BW production capabilities might be “hidden in plain sight” in a dual-capable facility, which could be diverted secretly to BW agent production campaigns between runs of a legitimate commercial product. For example, pharmaceutical plants routinely engage in the production of antibiotics in batches of 100,000 to 200,000 liters, and vaccines in

batches ranging in size from 150 to 3,000 liters; both types of facilities could be employed for the large-scale production of BW agents. Since proliferators in countries such as Iraq do not subscribe to Western standards of biocontainment, environmental protection, or worker safety, their BW facilities often lack clear “signatures” of work with hazardous pathogens. Similarly, while the manufacture of specialized biological munitions or submunitions would be incriminating, simple delivery systems such as aerosol sprayers and crop-dusters are dual-capable and hence more ambiguous.

Thus, the challenge facing a BWC compliance regime is to assess intent. Article I of the BWC states that the “types and quantities” of a microbial or toxin agent present at a facility must be consistent with legitimate, peaceful purposes. This requirement means that the facility must demonstrate to the satisfaction of the inspection team that each major piece of production equipment serves a legitimate purpose. Some workshop participants argued that over time, a cover story may be difficult and costly to maintain. Thus, if the inspectors discover a significant discrepancy for which a persuasive explanation is lacking, this finding would raise the level of suspicion and political pressure on the proliferator. But flaws in a cover story may only emerge if one examines the site carefully and has sufficient background data to recognize anomalies. For example, the inability of Iraqi officials to provide a plausible explanation for 17 tons of missing culture medium provided strong evidence to UNSCOM that Iraq had engaged in large-scale production of BW agents.

“Tacit knowledge” on the part of inspectors may also provide insights into intent. Dual-capable biological facilities are highly ambiguous, yet inspectors who have worked in Russia and Iraq say they often have an intuitive feeling when a facility is suspicious. While inspectors obviously can-

not include gut feelings or value judgments in an inspection report, their intuition may inspire lines of investigation that turn up solid information.

Thanks to rapid advances in biological detection technologies, DNA probes and the polymerase chain reaction (PCR) can identify even a few bacterial cells or viruses present in a sample. It was pointed out, however, that one must distinguish clearly between the analytic accuracy of a sampling technique (is a particular microorganism present?) and the diagnostic accuracy (what is the intent behind its presence?). While extremely sensitive methods such as PCR can detect BW agents in minute quantities, they can also amplify trace contaminants and may therefore yield false-positive results. Thus, merely finding a BW agent at a dual-capable facility does not necessarily mean that the site is noncompliant. Ideally, the BWC compliance regime should have a number of different components that interact synergistically, so that inconsistencies among various types of evidence raise suspicions. At the same time, a requirement for corroborating evidence would reduce the incidence of false positives.

Industry representatives and other participants expressed concern that ambiguous evidence or inspector prejudices could yield suspicions where none are warranted, damaging a company’s hard-won reputation. For example, since small mistakes in declarations and production records are inevitable, how will BWC inspectors distinguish between a real violation and sloppy recordkeeping? It was noted that the International Atomic Energy Agency (IAEA) has generally been able to distinguish between routine errors and real anomalies at nuclear facilities and does not view incompetent reporting as necessarily implying guilt. However, IAEA monitoring requirements may be less complex than those associated with the BWC. Another participant suggested that the response of the host facility when the inspection team finds an error

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would influence how it is perceived. If the inspected facility is innocent, the manager will probably acknowledge the discrepancy and cooperate with the inspectors to resolve it. Of course, such apparent cooperation might also be part of a disinformation effort or cover story.

The U.S. pharmaceutical industry worries that if challenge inspections are based on an assumption of guilt, companies will have to go to great lengths to prove their innocence and, in the process, will compromise valuable confidential proprietary information. For example, providing detailed justification for the use of individual fermentors could force a company to reveal sensitive CPI, such as manufacturing sequences or the exact production capacity of the facility. Another participant responded that inspectors typically focus on specific questions and will not need to review *all* of a facility's records or to determine its total production capacity. Moreover, the facility will have the right to manage access to sensitive records. The discussion suggested that it may be difficult to determine the gains and losses caused by inspections in advance. Much will depend on the circumstances of the inspection, the skill of the inspectors, and the practices of the inspected facility.

When the results of an inspection are ambiguous, the determination will probably be made that the allegation remains unproven—even if some countries possess compelling but sensitive intelligence information that cannot be released publicly. Conversely, an “unproven” verdict could unfairly damage the reputation of an innocent company or government. It was suggested that to avoid this outcome, the inspected facility should have the right to review a copy of the draft inspection report before the inspectors leave the site so as to clarify any ambiguities and minimize any CPI included in the report. Industry participants noted, however, that such a review would not solve the problem of ambiguities that are a matter of interpretation rather

than fact. Others cautioned that inspectors should not be put under pressure to change their findings.

### Scope of Declarations

Defining the declaration criteria will be a complex task. If the triggers for declaring relevant facilities are specified too narrowly, important dual-use facilities capable of clandestine production of BW agents will be excluded, reducing the effectiveness of the compliance regime. Yet if the criteria are defined too broadly, the number of declared sites will be overly large, with an undue emphasis on Western industrial sites.

Participants agreed that the scope of declarations should cover biodefense facilities, human and veterinary vaccine plants, and high-containment (BL-4) laboratories that work with the most dangerous pathogens, but beyond these facilities there was a divergence of views. The advantage of drawing the line at BL-4 facilities is that they are few in number and easy to identify, yet such labs are found in only a few countries and are unlikely to be used by most BW proliferators. Some participants noted that while BL-4 facilities would be required for hazardous activities in advanced industrial countries, such safety precautions may not be as important to other countries. Thus, BL-4 facility inspections may have limited value in ferreting out a BW program. Conversely, microbiology laboratories operating below the BL-4 level are extremely numerous and difficult to identify because containment level is defined primarily as a function of procedures rather than hardware and hence can change easily from one day to the next. Several participants argued that the best differentiator would be the biological agents and toxins a facility possesses rather than its containment level. Relatively few facilities work with the putative BW agents that have been listed by the Ad Hoc Group.



A basic problem with regard to the scope of declarations is that Western countries have a large number of industrial complexes in the pharmaceutical and biotechnology sectors, whereas developing countries generally do not. Thus, devising declarations to capture small-scale facilities in developing countries that have technical capabilities relevant to the BWC would also cover hundreds of Western industrial sites that are presumably of lesser compliance concern. While some Western countries have argued for imposing geographical quotas on the total number of visits to declared facilities, Non-Aligned Movement (NAM) countries have rejected this approach as “discriminatory” because they have only a small proportion of declarable facilities but would be subjected to an equal number of visits. One solution that might be acceptable would be to require a minimal declaration consisting simply of the name and address of all dual-use biological facilities, comparable to the one-page declaration form for producers of “discrete organic chemicals” under the CWC. Even such minimal declarations would increase transparency and make it easier to identify suspect facilities, and potential proliferators would be put on notice that their dual-capable plants would be kept under observation. However, some participants felt that such minimal declarations would not be meaningful and would be a nuisance to industry.

Problems associated with declarations of academic research laboratories were discussed. Pharmaceutical production is characterized by standard operational procedures and extensive documentation, and microbial cultures used for production are generally well characterized and documented. In contrast, industrial and academic microbiologists often collect microorganisms from exotic locales and retain them for future study without bothering to classify them by genus and species. Moreover, most microbiological research laboratories do not inventory the contents

of their storage refrigerators, which would require considerable effort. To avoid creating serious loopholes, however, it was suggested that academic and industrial research laboratories be held to the same declaration standard as production facilities, since otherwise BW proliferators might pursue illicit activities under academic cover. Indeed, universities played an important role in Iraq’s BW program. The BWC compliance protocol might therefore require the destruction or cataloguing of microbial culture collections if they are likely to contain hazardous pathogens.

## Challenge Inspection Procedures

### Mandate for Challenge Inspections

Some participants felt that the mandate for a challenge inspection should not be too narrow—such as the alleged presence at a facility of munition-filling equipment. If that piece of intelligence turned out to be wrong, the inspection would be effectively over, no matter how suspicious the facility might appear on other grounds. Industry participants stated, however, that open-ended inspections not based on a specific allegation would be unacceptable, and that challenge inspections should not be used as “fishing expeditions.”

Another concern is that challenge inspections that repeatedly yield negative or ambiguous results could erode the credibility of the compliance regime or allow BW proliferators to exploit the lack of hard evidence as a “seal of approval” implying innocence. Indeed, both Libya and Iran have called for international inspections when they believed it would ease political pressures on them. Thus, much as a good lawyer rarely asks a question of a trial witness without knowing the answer in advance, governments will probably request a challenge inspection only when they believe there is a reasonable likelihood of finding unambiguous evidence of a violation. Even

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if no “smoking gun” is found, challenge inspections may uncover falsehoods, anomalies, or defective cover stories, and enable states parties to increase the political pressure on proliferators by forcing them to explain their activities. Of course, outcomes will depend on the luck and the skill of the inspectors and those they inspect.

### Screening of Challenge Inspection Requests

The screening mechanism for challenge requests should aim for an optimal balance between two competing goals: allowing the BWC inspectorate to address states parties’ compliance concerns and protecting sensitive industrial and government facilities from frivolous or abusive inspections. To achieve the right balance, one needs to consider the geographical distribution within the executive council making the decision, and what percentage of votes would provide insurance against abusive challenge requests while permitting legitimate challenge requests to go forward.

Precedent exists for various approaches. The CWC has a “red-light” approval mechanism, in which three-quarters of the 41-country executive council must vote to *block* a challenge inspection. This approach is more effective at deterring violators but runs some risk that a frivolous request may be approved. In contrast, the Comprehensive Test Ban Treaty (CTBT) has a “green-light” approval mechanism, in which 30 of the 51 countries on the executive council must vote to *approve* a challenge request. This approach rules out frivolous requests but may make it more difficult to get legitimate ones approved.

Some believe that the U.S. decision to accept a green-light approval mechanism for on-site inspections under the CTBT may have set a precedent that will make it more difficult to adopt a red-light procedure for the BWC compliance protocol. While a few

countries may push for a red-light system, it is more likely that debate in the Ad Hoc Group will focus on the choice between a low-vote or high-vote green-light procedure. Under a strong green-light system, a challenge request by the United States or another Western country could be foiled if the NAM countries vote as a bloc. In contrast, a green-light filter requiring only a 25% approval vote would not be all that different from a red-light filter requiring a 75% disapproval vote.

The U.S. pharmaceutical industry has stated that it prefers a strong green-light approval mechanism to minimize the threat of inspections that could disrupt plant operations or threaten CPI. At the same time, however, suspected BW proliferators in the Ad Hoc Group also favor a green-light filter to make it harder to get challenge requests approved. Political factors, such as sensitive bilateral or trade relationships, may also influence executive council votes on challenge inspections. Consider the possible situation in which the United States requests a challenge inspection and backs it up with strong evidence, but the European Union wants to sell a fleet of Airbus aircraft to the country in question and believes it would be an inopportune moment for a confrontation.

Because of such unpredictable political factors, it is difficult to develop general rules for choosing an appropriate filter mechanism. One workshop participant advocated a hybrid mechanism involving a green-light system for challenge inspections of facilities, combined with a red-light system for field investigations of alleged use or suspicious disease outbreaks, which would be less likely to be frivolous or abusive.

### Challenge Inspection Timelines

The timeline for challenge inspections under the BWC compliance protocol may draw on two precedents. Under the CTBT, the executive council has 96 hours to delib-

erate *before* approving or disapproving a challenge-inspection request. Under the CWC, in contrast, the executive council deliberates *after* the inspection team has already been dispatched to the point of entry. If the inspection is not halted, the inspected state party must provide some access no later than 108 hours after the inspection team arrives in-country, or 120 hours after the initial notification. However, the CWC timelines are based on a worst-case analysis of the minimum time required for the most sensitive sites to prepare. The vast majority of biological facilities will not need that much time to protect CPI or national-security information.

The time required to clean up a BW production facility depends on the nature and technological sophistication of the facility. While the most advanced plants have “clean-in-place” systems that can sterilize fermentors in a few hours, some production facilities would require as much as a few days for a thorough clean-up. Certain states suspected of developing BW that are also participating in the Geneva talks are apparently trying to stretch out the timeline for challenge inspections so that they have more time to prepare. While it is always possible that a proliferator will make a mistake and leave behind telltale traces of a BW agent, the odds are low that routine sampling and analysis would detect them.

Nevertheless, other indicators of a BWC violation at a dual-use facility may be present. Pharmaceutical or vaccine production involves a great deal of documentation, including logs and computer records that would take considerable effort to doctor or forge. The cost of maintaining a detailed, credible cover story (including a separate set of record books) in a declared dual-use facility could increase the expense of a BW program so much that potential proliferators might be deterred. Record audits might be complicated by certain industrial practices, however, such as the destruction of batches without documentation.

Industry representatives also expressed concern that audits of manufacturing records could reveal substantial CPI. In proving itself innocent of a BWC violation, a company might have to reveal critical trade secrets that would put it at a competitive disadvantage. Another participant suggested that CPI might be protected if the inspectors focused their initial audit on less sensitive production records such as orders, shipments, and inventories of raw materials. But industry representatives responded that to one versed in the field, a considerable amount of CPI could be extracted from these records.

### Managed Access and Dispute Resolution

The CWC has “managed access” provisions that allow states parties to limit or deny access to a facility for national security, proprietary, or constitutional reasons, while offering alternative means to address the inspectors’ compliance concerns. It is likely that the BWC protocol negotiations will draw on this precedent. The troubling question with managed access is: after an inspected facility attempts to protect its sensitive information, will the inspectors be granted enough access to make a useful determination of BWC compliance?

Managed access seeks to give the inspectors only that degree of access to a facility needed to address a compliance concern, without enabling them to understand proprietary aspects of the manufacturing process. During a managed-access negotiation under the CWC, an inspected facility that denies access to a commercially sensitive area is obligated to “make every reasonable effort” to provide alternative means of addressing the inspectors’ compliance concerns, whether by record audits, interviews with plant personnel, or some other approach. Ultimately, however, the inspected state party—presumably in consultation with the inspected company or facility—has the prerogative to limit or

deny access. If a violator is deliberately seeking to deceive or obstruct the inspection team, such abuses cannot be prevented. Although there may be legitimate reasons to deny access, a consistent pattern of denial would be reflected in the inspection report and could raise suspicions of non-compliance. Thus, the threat of a negative inspection report might give the inspection team some leverage.

### Sampling and Analysis

Most workshop participants agreed that sampling and analysis should not take place routinely but only when a particular violation is suspected, and then only when the pre-test suspicion is greater than the probability of a false-positive result. Industry representatives stated that while they would consider opening up the fermentation, recovery, and purification portions of a pharmaceutical plant for visual inspection, they would not permit sampling and analysis.

An alternative to managed access would be to devise technical approaches to sampling and analysis that safeguard CPI. Some workshop participants proposed that before a sample of microorganisms from a pharmaceutical production line could be analyzed, on-site personnel would first inactivate the sample by heating. They would then partially digest the microbial DNA with a “restriction” enzyme to disrupt any proprietary DNA sequences while still leaving enough DNA intact to identify suspicious BW agents.

Industry representatives still expressed concern that a positive or ambiguous analytical result caused by background contamination or a problem with the reliability of the analytical technique could cast a pall over an innocent company’s reputation. For this reason, industry participants stressed the importance of devising “validated” sampling and analysis procedures that (1) give reliable and consistent results; (2) can

be performed rapidly (preferably on-site); and (3) will be approved by the U.S. Food and Drug Administration (FDA) and other government regulatory agencies as consistent with licensed manufacturing processes. If BWC inspectors were to conduct unvalidated tests during the inspection of a pharmaceutical plant and obtain ambiguous results, they could jeopardize the plant’s manufacturing license. An industry representative noted that it could take three to five years of development and testing to come up with validated sampling and analysis procedures that would be acceptable to industry.

Biomedical sampling of plant workers raises a host of constitutional and privacy issues. While the analysis of IgG antibodies present in blood would provide the most information about exposure to BW agents, sampling of saliva for IgA antibodies would be less invasive than drawing blood and might be politically more acceptable.

### Contents of the Inspection Report

The CWC and the CTBT do not allow the treaty organization to decide whether a violation has occurred. Instead, each member-state has the prerogative to analyze the inspection data and draw its own compliance judgements. Workshop participants agreed that assessing compliance under the BWC protocol should proceed along the same lines. Inspectors should record only factual observations in their reports, including the extent of cooperation provided by the inspected state party. Ambiguous sampling results might be reported either as negative or as unproven.

A few participants saw value in creating a technical advisory committee associated with the BWC organization that would analyze inspection reports and provide a nonbinding opinion on whether the findings are consistent with nonprohibited activities. For example, if undeclared anthrax is found inside a facility, the advisory com-



mittee would assess the significance of this finding in terms of the likelihood of natural sources of contamination.

### Lessons Learned from Trial Challenge Inspections

Findings were presented from U.S. Department of Energy (DOE) trial challenge inspections of a DOE laboratory and an academic facility in the United States, and formal British government trial inspections of four pharmaceutical sites in the United Kingdom (UK). The DOE trial challenge inspections led to the following conclusions:

1. *The trial inspections did not build confidence and, on the contrary, raised a number of suspicions that could not be resolved.* At the academic laboratory, sloppy recordkeeping led to frequent ambiguities. For example, the lab declared that it was not working on microbial pathogens, yet the inspectors found a refrigerator door clearly marked as containing Venezuelan equine encephalitis, anthrax, and plague cultures.
2. *A “BW template” can be overlaid on any complex biodefense site.* At the DOE laboratory, it was possible to find major components of a putative BW program within a few kilometer radius, including facilities for basic research in molecular biology and scale-up production of microorganisms. At the academic laboratory, management was so concerned about being unjustly accused of a BWC violation that it sent the staff home and refused to permit sampling and analysis because the results might be ambiguous.
3. *Adequate site preparation is difficult to achieve.* Even after multiple briefings, the sites were generally unprepared to meet the inspectors’ requests for information. One facility manager could not answer most

of the inspectors’ questions and delegated them to staff members who gave inconsistent answers, creating an impression of noncompliance.

Surprisingly, the results of UK trial challenge inspections differed 180 degrees from the DOE findings. British officials conducted trial challenge inspections of four pharmaceutical facilities: a pilot plant, a large-scale production plant, an R&D and production plant, and a vaccine production plant. No major problems arose in negotiating access or with public relations. Although the inspected facilities were only required to declare some of their activities, the entire site was regarded as lying within the inspection perimeter and as potentially relevant to the BWC. None of the site activities were forced to shut down during the inspection, and no restrictions were placed on inspector interviews with plant workers. In areas where access was restricted because of operating protocols, video cameras were employed as an alternative means of conducting inspections.

One reason for the divergent results of the DOE and UK inspections may have been differences in the underlying presumption of guilt or innocence. The DOE trials were more confrontational since they began with an assumption of noncompliance and sought evidence to support this hypothesis. In contrast, the British inspections explored the accusation of noncompliance against the possibility that activities at the site might be entirely legitimate. Thus, whereas the DOE inspectors tended to view inconsistent answers to questions as evidence of wrongdoing, the British inspectors were more tolerant of ambiguities. This difference in approach may explain why the UK trial inspections were more acceptable to the inspected facilities and caused less disruption.

The Australian, Canadian, and Dutch governments have also conducted preliminary trial inspections in which they found it was possible to satisfy BWC compliance

concerns without compromising CPI. The results of these trial inspections must be regarded with caution, however, since the psychological attitude of the inspectors is presumably different when inspecting a plant in their own country. During an inspection in a foreign country, the relationship between the inspection team and the challenged facility would probably be more confrontational. Thus, additional information is needed about the intrusiveness of trial inspections and the extent to which they accurately reflect the nature of true challenge inspections.

### Lessons Learned from FDA Inspections

An FDA official explained that to obtain a license from the FDA to market a drug or vaccine, a pharmaceutical company must share proprietary information with the regulatory agency (with the sole exception of financial data) and accept intrusive on-site inspections. Nevertheless, the manufacturer and the FDA both have a stake in making these inspections a success: the company seeks approval to market its product, while the FDA wants to protect and improve the health of the general public. Despite these incentives to cooperate, the FDA still occasionally finds evidence of deliberate fraud and falsification of records by pharmaceutical companies, although primarily by marginal firms under severe financial strain.

An FDA inspection of a pharmaceutical plant typically takes between two and seven days. The agency's inspectors are empowered to observe all parts of the manufacturing process and to ask questions. During "closeout," the inspectors report their findings to the plant management, listing observations that could be violations. The inspection report is automatically made available to the inspected company and can also be requested by the general public under the Freedom of Information Act (FOIA). Based on nine

volumes of federal regulations, FDA officials determine which portions of the report are CPI and hence are exempted from public release; protected categories include trade secrets and privileged information such as names and titles of individuals against whom legal action is taken. Individual FDA inspectors who deliberately release or sell information classified as CPI can be charged with a felony. National regulatory agencies in countries such as the UK, where the U.S. pharmaceutical industry markets its products, also have the right to conduct on-site inspections of U.S. plants and have their own procedures for protecting CPI.

### Nonchallenge Activities

#### Utility of Nonchallenge Visits

Although some participants questioned whether the BWC would be minimally verifiable even with challenge inspections, all agreed that without a provision for some type of challenge inspections, the BWC compliance regime could not be effective. There was disagreement, however, over whether the objectives of the regime could be accomplished with challenge inspections alone. In particular, would challenge inspections be sufficiently numerous and intrusive to deter violations and ensure that all relevant facilities are declared? Would "nonchallenge" visits be needed to complement or supplement challenge inspections, or would their benefits outweigh the costs? The workshop discussion raised a number of pros and cons of nonchallenge inspections, which are summarized below.

#### Pros

1. Nonchallenge visits might possibly detect the diversion of declared dual-capable facilities for BW purposes, forcing proliferators to resort to clandestine operations that would be

more costly and for which the importation of materials would be difficult. Periodic checks of declared facilities would also enable intelligence services to concentrate on fewer sites of concern. If declared facilities are not checked routinely, they could well become the sites of choice for illicit activities.

2. Since challenge inspections will be politically charged and could be blocked during the approval process, they might be too rare to have much deterrent value. The absence of inspectors on the territory of a proliferant state could lead to feelings of immunity. Thus, if transparency and deterrence are important goals of the regime, some form of nonchallenge visit may be essential.
3. The administrative burden for declared facilities liable to receive nonchallenge visits should be manageable because the visits would not have to be carried out at short notice to deter misuse of these facilities. The principal risk to the proliferator would not come from traces of illicit material that had not been removed in preparing for the visit, but rather from inconsistencies in the long-term cover story revealed by interviews and record audits during the visit.
4. Nonchallenge visits would check the accuracy of declarations and maintain the skills of a professional inspectorate, who would not be fully employed by conducting relatively infrequent challenge inspections. In this way, the inspectors would get practice in making inspections more effective.
5. Nonchallenge visits would familiarize officials of the inspected facility and the host state party with inspection procedures and reassure them that their CPI can be protected during more intrusive challenge inspec-

tions, raising the comfort level for both the inspectors and industry.

6. From the standpoint of the inspectors, a nonchallenge visit would provide useful “baseline” information about a facility or a region, making it easier to distinguish illicit activities from normal practice. For example, if a challenge inspection of a biopesticide plant found gaps in the production logs, the anomaly might be attributable either to sloppiness or to illicit activity. If the inspectors had visited the plant repeatedly in the past, they would have a better idea of its operating standards and could design more useful challenge inspections.
7. Some pharmaceutical plants are already subject to routine inspections under the CWC.

#### Cons

1. For purposes of deterrence, it is not the total *number* of inspections but rather their *outcome* that counts. A potential proliferator would be deterred more by one challenge inspection of an undeclared facility that turned up incriminating evidence than by several nonchallenge visits to declared facilities.
2. Nonchallenge visits would have little deterrent value because they would apply only to declared facilities, yet illicit activities would be more likely to occur in clandestine facilities. During a challenge inspection, lucky inspectors might stumble upon compelling evidence of a violation, but nonchallenge visits to declared facilities would be very unlikely to find such evidence.
3. Nonchallenge visits could give rise to false confidence in treaty compliance, which would arguably be worse than no confidence at all.
4. Extensive nonchallenge inspections may drive direct and indirect costs to

excessive levels and, for some facilities, may pose the greatest threat to CPI.

5. Because the vast majority of declared facilities will be in Western countries, nonchallenge visits will only provide an effective deterrent if there is a quota of visits per country and site, combined with a system of weighted random selection. Without such a system, nonchallenge visits would simply burden the Western pharmaceutical industry, which presumably poses less of a compliance concern, while diverting scarce resources from suspect facilities in the developing world.
6. Industry fears that nonchallenge visits could unnecessarily jeopardize CPI and tarnish industry's good name without yielding offsetting benefits for treaty compliance. Unwarranted allegations might not be easily refuted and could cast a pall over a company's reputation. Indeed, pharmaceutical companies consider their good name with the public to be of equal if not greater importance than CPI.

### Clarification Procedure

While disagreeing on the merits of nonchallenge visits, workshop participants showed surprising unanimity on the need for a compliance tool that would be less politically charged than requesting a challenge inspection. Particularly valuable would be some mechanism for applying pressure on a state party that submits an inaccurate or misleading declaration, either deliberately or inadvertently. (Note that "state party" refers to the participating government and not to inspected sites or facilities that are privately owned.)

The CWC sets a precedent in providing for bilateral consultations to clarify am-

biguities, but it lacks a more formal clarification mechanism. The IAEA also has the power to initiate special inspections of undeclared nuclear facilities on the basis of information that is shared by states parties but not made public. One possibility for the BWC protocol would be that if informal consultations were insufficient to clarify a questionable declaration, a concerned state party could request that representatives of the BWC organization conduct a "clarification visit" to the capital of the suspect country. In contrast to a challenge inspection, which would be based on the formal allegation of a treaty violation at a particular site, a clarification visit would seek to determine whether a facility should have been declared or whether significant information is missing from the declaration. Such a visit would provide a political means to pursue and clarify these questions with officials from the country of concern, and might carry sufficient weight to persuade the country to submit a revised declaration. Since the political threshold for requesting a challenge inspection will probably be high, having a mechanism for addressing faulty declarations would permit a gradual escalation of intrusiveness.

The primary purpose of the clarification procedure would be to clear up errors or omissions and would not necessarily include on-site visits to the disputed facilities. Workshop participants noted that while the on-site inspection of a contested facility might be arranged by mutual agreement, clarification visits should not serve as "a poor man's challenge inspection." Moreover, care must be taken that clarification visits are not exploited by proliferators to reduce pressure for stronger actions that might be warranted.

How would clarification visits be initiated? Intelligence-capable countries might share their concerns about questionable declarations with other states parties and ask the BWC organization to investigate.



Alternatively, since the organization's technical secretariat would review all declarations, it would be in a strong position to conduct clarification visits on its own initiative.

## Field Investigations

### Purpose of Field Investigations

Three possible BW-related contingencies could result in a suspicious outbreak of disease: (1) the overt or covert use of biological weapons for military or sabotage purposes; (2) the accidental release of a BW agent from a clandestine development or production facility; or (3) the open-air testing of BW agents, such as was carried out by the Soviet Union and Iraq. The Ad Hoc Group currently favors field investigations of BW use, but a few countries (notably Russia) object to investigations of accidental release or testing. While some countries have proposed developing separate procedures for investigating these three types of incidents, the lines between them are blurred. Since small-scale BW use may have characteristics similar to those of an accidental release, they may not be distinguishable in practice—except, perhaps, by the location of the outbreak. For this reason, the regime should be sufficiently flexible to address a wide range of scenarios.

It was suggested that in order to warrant a field investigation, some evidence must be present indicating that the origin of a disease outbreak is nonnatural. Possible indicators might include the following:

- The recovery of a biological munition (which would be extremely rare);
- An “explosive” outbreak of disease in a large population, rather than the gradual rise from a small number of precursor cases typical of a natural epidemic;
- The incidence of pulmonary infection with a disease agent that is rarely contracted by inhalation;

- The appearance of a vector-borne disease outside the normal geographic range of the insect or animal carrier;
- Data on the molecular characterization of a microbial pathogen suggesting it is not the naturally occurring species or strain;
- Reports of a suspicious cloud released from a helicopter or aircraft.

In many cases, however, the evidence for a link between an unusual disease outbreak and biological warfare will be equivocal. Natural emerging diseases such as AIDS, Ebola fever, and Legionnaire's disease result from ecological changes catalyzed by human activities, and may appear suspicious when they first appear on the scene. Indeed, the outbreak of Legionnaire's disease in Philadelphia in 1976 and the hantavirus outbreak in New Mexico in 1993 both met the criteria for a suspicious outbreak yet turned out to have natural causes.

Since emerging infections are on the rise, it would be counterproductive for the BWC organization to investigate what are actually natural outbreaks. For this reason, epidemiologists should set a high standard of evidence before concluding that an unusual outbreak of disease is associated with the covert development, production, or use of biological weapons. In the absence of compelling evidence of BW use, a nonpolitical body such as the World Health Organization should conduct the initial epidemiological assessment. Fortunately, the tools of epidemiology are specific enough to distinguish rapidly between natural and unnatural origins. In the case of the hantavirus outbreak, it took only two weeks for scientists to isolate the causative microorganism and to identify the rodent vector. If the initial epidemiological assessment of an unusual outbreak turned up evidence suggestive of a nonnatural etiology, the BWC executive council could then launch a follow-on investigation.

### Cooperative vs. Noncooperative Settings

Investigations of alleged use may occur in either a cooperative or noncooperative setting. A state party that claimed to have been attacked with a biological weapon would presumably request a field investigation and cooperate fully with it. But if two states parties used biological weapons against each other, or a state party employed BW against a rebellious minority or subnational group, the responsible governments would have no interest in requesting an investigation. In this case, a third state party that was not the victim of the attack would have to request a field investigation on the territory of the alleged perpetrator(s), who presumably would be reluctant to cooperate. An accidental-release incident similar to the 1979 Sverdlovsk anthrax epidemic would also require an investigation on the territory of a nonrequesting state party. Such an investigation is likely to be confrontational and would therefore have to be conducted by an organization with the necessary statutory authority under international law.

Although states parties are under an ethical obligation to report serious disease outbreaks, some countries may hesitate to do so because the resulting negative publicity could cause economic damage. For this reason, field investigations should remain fairly low-profile. One workshop participant stressed the utility of relying on market “pull” rather than technological and political “push” to obtain information on unusual outbreaks of disease. By promoting a norm of reporting epidemics over the Internet and creating a global infrastructure for this purpose, a great deal of useful data would become available. It was therefore suggested that all BWC states parties be given the capability to exchange and evaluate epidemiological data. To the extent possible, this system would be depoliticized, for example, by referring to “syndromes” rather than diseases. In the case of another Sverdlovsk-type incident,

unofficial information might start to pour out of the affected area over the Internet, perhaps making it possible to determine the characteristics of the disease outbreak quite rapidly.

Other participants criticized the “market-pull” scenario as unduly optimistic. Those countries where Internet access is most needed are the ones most resistant to the free flow of information, such as Iraq, Iran, China, Libya, Syria, and North Korea. Even Russia, despite its significant moves in recent years toward greater scientific freedom, has recently gone back to attributing the cause of the Sverdlovsk anthrax outbreak to contaminated meat. Advocates of the market-pull approach replied that the only way a country can suppress the flow of information completely is to cut itself off from the rest of the world, which would be self-defeating.

### Procedures for Initiating Field Investigations

Should the screening mechanism for approving requests for field investigations differ from that for challenge inspections of facilities? Several participants argued that the primary aim of field investigations should be to establish a mechanism requiring states parties to accept a short-notice, on-site investigation of any future Sverdlovsk-type incident. At the time of the Sverdlovsk outbreak, experts in the West lacked reliable epidemiological information to support the allegation of an accidental release of anthrax spores. It was only 15 years later, when investigators examined pathological samples (hidden during the outbreak by local Soviet physicians) and gathered epidemiological data on-site, that it was possible to obtain evidence that could be made public and was persuasive enough to convince critics of the U.S. government’s case.

Some workshop participants spoke in favor of a red-light approval mechanism for

field investigations, which would make it harder to block legitimate requests for political reasons. Other participants favored a green-light filter and compelling evidence of use, since a field investigation that yielded no proof of wrongdoing would seriously damage the credibility of the process. However, the requirement to provide compelling evidence when requesting a field investigation could become a catch-22, demanding information in advance that could only be obtained on-site. One participant proposed a possible compromise formula, in which the invitation by a state party to conduct a field investigation *on its own territory* would be approved by a red-light process, while the request to conduct a field investigation without invitation *on the territory of a third party* would require the more stringent green-light approval process.

### **Role of the World Health Organization**

What role should WHO play in field investigations under the BWC protocol? Until recently, WHO was reluctant to get involved in BWC compliance monitoring because of concern that the organization would become unduly politicized. Although the current WHO leadership is more receptive to some kind of involvement, several workshop participants argued that inviting direct WHO participation in BWC investigations would be a serious mistake.

One problem is that as a UN agency, WHO has significant constraints on its activities. First, it is primarily an administrative body whose investigation teams are staffed by national public-health agencies, such as the CDC. Second, although WHO collaborating centers can report epidemiological data without the permission of the host governments, a WHO investigation team cannot enter a country without being invited in. For this reason, a separate BWC investigation team would have to be empowered to conduct field investigations on

the territory of states parties to the BWC protocol, without the need to obtain approval in advance.

Some participants suggested a two-track system. To avoid politicizing WHO's participation, the WHO Director-General would inform the BWC organization about unusual outbreaks of disease in various parts of the world, with an emphasis on those cases suggestive of nonnatural etiology. In cases where circumstantial evidence of BW use was strong, the BWC executive council could initiate a field investigation directly. In all other cases, however, WHO would perform an initial assessment and would make its preliminary findings available to the BWC organization. If this preliminary assessment turned up evidence suggestive of BW use or accidental release, the executive council could then vote to initiate a field investigation under the BWC protocol. In this way, WHO would make relevant epidemiological information available to the BWC organization but would not be put in the politically sensitive position of having to make judgements on whether biological weapons had been used.

Workshop participants agreed that neither the head of the BWC organization nor the Director-General of WHO should have standing to request a field investigation, which should remain the prerogative of states parties. The head of the BWC organization would merely bring suspicious disease outbreaks to the attention of the executive council, which would then vote on whether or not to initiate field investigations.

### **Composition of Field Investigation Teams**

Industry representatives stated that if field investigations could involve inspections of facilities, the investigators must be drawn from a standing, professional inspectorate that is fully accountable for its actions and thus has a strong incentive to protect CPI. Other participants responded that it would

not be cost-effective to establish a professional inspectorate for field investigations, which would occur sporadically. A possible model is SCORPIO, a multinational group of BW experts and epidemiologists established by the Swiss government during the 1991 Persian Gulf War to investigate possible Iraqi use of biological weapons. Since the end of the war, SCORPIO has continued to exist; its members are trained volunteers who have agreed to be called up on short notice in an emergency, such as the use of biological weapons by terrorists.

Various possible approaches to recruiting, certifying, and training inspectors each have advantages and disadvantages. One workshop participant suggested a hybrid solution in which the field investigation team would consist of a small core group of epidemiologists employed fulltime by the BWC organization, supplemented by a larger group of outside experts who would be thoroughly trained and selected on a case-by-case basis from a preapproved list. In addition to participating in field investigations, the staff epidemiologists would monitor disease outbreaks around the world on a continual basis. Under Article X of the BWC, which provides for enhanced international cooperation among states parties in the peaceful applications of biology, the staff epidemiologists might also be made available to advise developing states parties on public-health programs to combat infectious disease. To ensure the integrity of the BWC organization, however, its cooperative activities under Article X would have to be kept entirely separate from its compliance-monitoring activities under Article I.

### Field Investigation Procedures

The faster the investigation team gets to the site of an alleged use or accidental release, the better for purposes of detection and deterrence. Accordingly, workshop participants agreed that timelines for field inves-

tigations should be significantly shorter than those for facility investigations. Participants also agreed that environmental samples of air, water, soil, and wild animals should only be taken if the analytical results can be interpreted clearly. Since environmental samples might contain unknown background contamination, they must be compared with control samples.

Typically, field investigators will only enter buildings to examine patients in hospitals or corpses in morgues. If, however, a particular facility has been linked to an unusual outbreak of disease (as occurred at Sverdlovsk), some mechanism will be needed to switch to a facility inspection. Perhaps the head of the BWC organization could convene a meeting of the executive council and request permission for the field investigation team to enter the suspect facility. While the executive council was deliberating, the inspection team would establish a perimeter around the facility to prevent the host country from removing any incriminating evidence.

If an unusual outbreak of disease took place near a declared biological production facility such as a vaccine plant, the investigators might ask to sample the production line to make sure the disease-causing microorganism was not being produced there. In this case, an innocent facility would presumably cooperate with the inspectors to resolve the compliance concern as quickly as possible.

Is managed access needed in the context of a field investigation, particularly in a noncooperative setting? Workshop participants opposed applying managed access to environmental sampling, interviews with disease victims, performance of autopsies, or access to biomedical samples already available at the inspected site. Managed-access procedures might, however, be applied to inspections of buildings, interviews with plant workers, and the taking of blood and other biomedical samples from individuals other than patients.



## Conclusions and Suggestions for Future Work

While some participants expressed disappointment that the workshop had not reached closure on more issues, others recognized that consensus was an unrealistic goal given the broad range of opinions and interests represented. The primary purpose of the exercise was to bring together constituencies that do not communicate on a regular basis and to get their ideas and concerns out on the table for discussion and clarification. The group did achieve convergence on a few issues, such as the value of exchanging epidemiological data over the Internet, the desirability of a clarification procedure to pursue missing or faulty declarations, the need for field investigation teams to include both permanent staff and

experts selected from a preapproved list, and the suggestion that WHO play a supportive but depoliticized role in field investigations.

With respect to future work, industry representatives suggested that an in-depth discussion of trial inspection results would be quite useful. Other participants suggested that it would be valuable to examine in detail how an epidemiological field investigation would be conducted in an international political setting, perhaps by working through a detailed scenario in a table-top exercise followed by a discussion of lessons learned. During such an exercise, it would be useful to have participation from some developing countries with different views on BWC compliance issues, to create a more realistic political context.



## Appendix A: Keynote Address

### The Control of Biological Weapons: Retrospect and Prospect

*Ambassador James F. Leonard*

The Biological Weapons Convention, as conceived and negotiated in 1971 and 1972, was a rather unusual arms control treaty. Useful lessons can be drawn from that experience and from the current effort to develop verification procedures. I will also attempt to visualize the role that the BWC regime might play several decades into the future.

Let me try to summarize what U.S. officials had in mind 25 years ago in pushing for an arms control treaty with two unique characteristics. First, the BWC had no verification provisions; and second, it dealt with a class of weapons that we had destroyed unilaterally before the negotiations got seriously underway. We thus ran directly counter to the conventional wisdom that arms control must be verified or the bad guys will cheat, and that weapons must be given up only when the action is reciprocal or the bad guys won't negotiate.

Subsequent developments, such as the Sverdlovsk incident and Yeltsin's acknowledgment in 1992 that the Soviet Union had violated the BWC, suggest that these two principles were more valid than we thought back in 1969. Nevertheless, I would argue that the U.S. decision to negotiate the BWC was correct at the time, is enhancing our security now, and will continue to do so in the future.

#### Origins of the BWC

The original idea of a biological weapons treaty was not American but British. In 1968, the United Kingdom began arguing on the record that biological weapons and chemical weapons were so different, particularly in the possibilities for verification, that the disarmament conference in Geneva should abandon the long-sought goal of a combined ban on their development, production, stockpiling, and transfer, complementing the 1925 Geneva Protocol banning use. "Let's do BW first," the British argued, "because it is a much easier task: BW is regarded with even more abhorrence than CW, BW is more dangerous, and we can go on to do CW later."

To the best of my recollection, none of the other NATO allies agreed, while the neutral and nonaligned countries, led by the redoubtable—and wonderful—Mrs. Alva Myrdal of Sweden, were strongly opposed. The Soviets, who tended to pander to the nonaligned, flatly dismissed the concept.

The U.S. domestic political context was important here. The United States had been employing tear gas in combat in Vietnam and was being charged with violating the 1925 Geneva Protocol. In a way, the tear-gas issue had become a stand-in for the unpopular U.S. involvement in Vietnam. The focus on tear gas was prominent both within the United States and internationally. When the United States moved toward the British position favoring a separate BW treaty in 1969, many saw this shift as a ploy to defuse the tear-gas issue and with it the Vietnam question, and also as a way to postpone indefinitely any

serious discussion of chemical arms control. In fact, there was considerable truth to both charges. These political considerations made our efforts to sell a separate BW treaty an uphill task.

The UN General Assembly of 1969 brought this problem home to me rather directly. I led the delegation from the U.S. Arms Control and Disarmament Agency (ACDA) to the United Nations in New York, where we had the task of defeating a resolution proposed by Mrs. Myrdal and drafted by her young legal adviser, Hans Blix, declaring the use of tear gas or herbicides in armed conflict to be a violation of the Geneva Protocol and thus of international law. We denounced the resolution strongly and lobbied hard against it. The vote, on December 16, 1969, was 80 in favor and only 3 opposed (Australia, Portugal, and the United States), with 36 abstentions.

### Washington Policy Debates

The policy-making process in Washington on chemical and biological weapons (CBW) had continued throughout 1969 and reached its conclusion almost at the same moment the UN General Assembly was voting in New York. The National Security Decision Memorandum (NSDM) of late 1969 unilaterally renouncing biological weapons was certainly influenced by the tear-gas issue, especially with respect to U.S. domestic opposition, but it would be unfair and wrong to depict it merely as a response to domestic politics. Rather, I believe it was based on a pragmatic analysis of how U.S. security interests could be best served. The arguments employed in the internal U.S. government debate were the same ones we began to use in Geneva after President Nixon had approved the NSDM. These arguments eventually won the support of other governments, although in Russia this process apparently took almost 20 years.

Most of you are quite familiar with these arguments. Biological weapons are more of a threat to the nation that possesses them than to any potential adversary. They are practically unusable in military terms but are suitable as instruments of terror if they escape responsible control. The best defense, it was then and is still argued, is not retaliation in-kind but protective measures and a first-class national health system, combined with other retaliatory capabilities. (Whether these capabilities should include nuclear weapons I will not address here, nor was it a question in Geneva in 1970–1971.)

I was not a participant in the Washington policy debates of 1969, but from colleagues who were present I had the impression that the arguments summarized above had general support. Certainly there were other points of view, but the uniformed services had never liked BW, nor was there a strong institutional backing for them as there was for chemical weapons. To the best of my recollection, however, there was no serious support for a unilateral renunciation of BW *without* a treaty. “If we are going to disarm, let’s at least try to bind others into a similar commitment,” seemed to be the consensus within the U.S. government.

### International Persuasion

The British statement in 1968 that verifying a ban on possession of BW was simply impossible made it out of the question for the U.S. administration to cook up a make-believe verification proposal. If we wanted a treaty, we had to argue that it was in the security interests of the United States and all other countries even without verification, which is

what we did throughout 1970 and into early 1971. We were quite successful with our allies once they had reflected seriously on the choices. None of them except the British had invested heavily in deterrence of BW or CW by the threat of retaliation in-kind. The other allies had relied on their conventional and nuclear capabilities to deter the use of chemical or biological weapons against them, and they did not even have very good defensive equipment.

The neutral and nonaligned states were more difficult to persuade, but not on the verification question. They strongly opposed splitting BW from CW. What they really wanted, though they never put it this baldly, was an unverified ban on the possession of both chemical and biological weapons as a norm of international law. Nearly all of them had zero capabilities in either area and were not interested in acquiring such, nor did they fear that their neighbors would do so; but they were somewhat concerned that an unreformed “imperialist-colonialist” power might threaten them with CBW. Historical examples included Japan’s use of chemical and biological weapons against China during World War II, fascist Italy’s use of chemical weapons against Ethiopia in 1936, and the almost-forgotten British use of chemical weapons in Afghanistan after World War I. Yet in a rather touching tribute to the growing respect for international law, the nonaligned tended to believe that even an unverified CBW ban would diminish the danger.

I don’t know if our relentless arguments throughout 1970 and early 1971 in favor of an unverified BW treaty led other governments, especially the nonaligned, to think that we would eventually change our position and apply the same logic to CW. We in the U.S. government knew that we would not. The Defense Department, from Secretary Melvin Laird on down, was adamant on the need for an improved offensive CW capability to deter the Soviets through the threat of retaliation in-kind, but other governments apparently did not recognize this fact.

The nonaligned did, however, believe Moscow’s assertions that it would never agree to split CW from BW. But in the summer of 1971 the Soviet Union, without any warning, did exactly that. I vividly recall the indignation of the Nigerian, Egyptian, and East European delegations when they learned that the Soviet ambassador would give a speech the next day completely reversing the Soviet position. Some of their sense of betrayal was also directed at the U.S. delegation for not having tipped them off, since the Soviets had given us several days’ notice of the policy change.

Once the Soviets changed position, the rest was easy. Superpower agreement meant something in those days. We had a joint U.S.-Soviet draft text in a few weeks. Not long after that we were able to get the support of our allies and of many nonaligned states. We submitted a text to the UN General Assembly that fall, and the treaty was opened for signature in early 1972.

### **The Road Not Taken**

Before turning to the future, let me offer a brief comment on the road not taken in the NSDM of 1969, namely unilateral renunciation of BW without a treaty. Unilateral disarmament has certain real merits that are sometimes proposed in areas of arms control where assessing compliance is difficult. For the United States, unilateral action avoids the political struggle involved in securing Senate advice and consent to ratification. In addition, a unilateral declaration is more readily altered if circumstances change, and it may offer a more flexible and less confrontational framework for dealing with suspected violations.

Had the Soviet Union only violated a unilateral commitment at Sverdlovsk in the late 1970s, for example, senior Soviet officials might have been more willing to acknowledge the breach and blame it on ignorant or irresponsible underlings.

For me, however, these arguments are outweighed by the advantages of a treaty. The language of a treaty is accepted by all parties, and the public negotiating record is available to help clarify the unavoidable ambiguities of even the most careful drafting. Compare, for example, the present confusing situation with regard to so-called “negative security assurances”—unilateral commitments by nuclear-weapon states not to use nuclear weapons against non-nuclear-weapon states. Above all, a treaty is stable, permanent, and in a democracy has much broader support than a presidential statement crafted out of public view by a handful of advisors. Unilateral policy pronouncements can be altered for what may be transitory considerations, as happened recently to the Russian position on “no first use” of nuclear weapons. Treaties, in contrast, endure and can be strengthened even when they have been violated, which is what is happening now with the BWC.

Despite our acknowledged inability to know exactly what is going on inside laboratories in countries such as Iraq or Iran, the BWC gives us a valuable legal and political instrument for detecting and dealing with the development, production, and stockpiling of biological weapons. Merely having the text on the books does not guarantee our security. But having a text that has been accepted and is sincerely supported by the vast majority of the 140 states parties does enhance our security. The negotiation and broad acceptance of a BWC compliance protocol will further strengthen the treaty and the international norm embodied in it.

### Future of the BWC

I would now like to say a few words about the future of the BWC. The effort now under way to develop a compliance protocol has excellent chances of succeeding, although I cannot offer any useful speculation on its final contents or the timing of its completion. I am also confident that the current effort will not be the last word in BWC verification.

To explain myself, I must step back from BW and look briefly at the role of arms control in creating a safer world, and its relationship to the more fundamental processes of political and economic development that are building a new and better international society. An excellent discussion of this process by Michael Mandelbaum appeared in the March 1997 issue of *Arms Control Today*. He argues that the “the post-Cold War settlement now in place in Europe is a triumph of arms control” and goes on to explain that this arms control regime “has been tied to, has depended on, and has been subsumed by international politics.”

These international and internal political developments have made the renewed danger of general war in Europe extremely unlikely, and I believe this situation will continue. The process Mandelbaum describes will deepen in Europe and spread to its southern and eastern margins and to other regions of the world. I don’t know precisely how long it will take, but some decades from now the entire zone of the Organization for Security and Cooperation in Europe—from Vancouver to Vladivostok—will enjoy the sort of mutual confidence across national borders that today obtains between the United States and Canada, between Norway and Sweden, or between Spain and Portugal. Still more decades later, these improved conditions will even spread to regions such as the Middle East, which look so desperate today.



During the long, slow transition to a new system of international relations, the global and regional arms control treaties of the past 40 years will be complemented by additional treaty regimes covering the full range of conventional weapons. Together, these treaties will provide a framework of norms, obligations, procedures, rules, and interactions that will foster political advances. These treaties will bring with them a matrix of verification procedures so penetrating, so ubiquitous, and so intrusive as to be unimaginable today. Total transparency in military matters will be the norm that is steadily and inexorably approached. Military secrecy will be seen, increasingly, as an unhealthy remnant of a previous era in which national security was protected by the balance of power.

### Societal Verification

Perhaps the ultimate in verification arrangements will be what Pugwash and others term “societal verification,” which means embodying in an arms control treaty the requirement that each party to the treaty must charge its citizens with blowing the whistle if they become aware that their government is cheating on its treaty commitments. Some regard societal verification as the *reductio ad absurdum* of verification, but I disagree. Certainly it is not contemplated that societal verification will stand alone, completely supplanting the adversarial type of verification this workshop is addressing. Nor is it contemplated that it could make a substantial contribution in states ruled by a ruthless dictatorship. Democracy, the rule of law, human rights, and the weakening of ancestral hostilities toward other peoples are all prerequisites for effective societal verification.

The advance toward societal verification will of course meet resistance. It will be argued that the advance of democracy will make unnecessary the sort of intrusive and even repugnant measures entailed in societal verification. Conversely, it will be argued that no democratization process, no enhancement of human rights, will ever protect citizens in some regions of the world against the vengeance of their governments or of their fellow citizens if they betray official secrets to the “enemy.”

Certainly it will take time. But I believe there is no real alternative, since it can be shown that neither nuclear nor biological weapons can be reliably eliminated without societal verification. Traditional adversarial-type verification simply cannot generate sufficient confidence to satisfy prudent skeptics in states that have a long history of conflict. To be specific, I cannot imagine a BWC regime that would command sufficient credibility throughout the Middle East to persuade the key governments of that region that all threats of biological warfare had been totally and permanently eliminated. This reality need not mean that important states in that region will remain outside the BWC regime or that they will rely on deterring BW attacks through the threat of retaliation in-kind. On the contrary, I believe that all states in the region will eventually accede to the BWC and work sincerely to strengthen its implementation.

Like the United States, however, states in the Middle East and other regions will not rely totally and exclusively on the BWC regime to deal with the BW problem. Defensive measures will play a proper “hedging” role for years to come. During that period, the BWC and its steadily improving verification regime will keep the process moving forward and make it easier to counter false charges and unfounded suspicions.

Eventually, the positive interactions fostered by participation in the BWC regime and the many other arms control and security structures that will be established, together with the economic and cultural exchanges that will develop over time, will build mutual

confidence that peace is not merely a truce or a breathing spell. At that time, total transparency, including measures for societal verification, will become possible even between countries such as Egypt and Israel, where such ideas are regarded today as unthinkable, subversive, and hopelessly idealistic.

Twenty or thirty years from now the BWC regime should be a mature system, universal and highly valued, though not without some continuing problems. The BWC should also be a relatively small but important piece of a much larger structure of global and regional arms control and security arrangements. We can hardly expect that in that relatively brief period mankind will have eliminated all possibility of war, whether in the Middle East, South Asia, East Asia, or elsewhere. But additional large regions of the globe—all of Latin America, for example—should have joined the Vancouver-to-Vladivostok zone of permanent peace. With the danger of war declining to very low levels, particularly among the most advanced and wealthy nations, it should become possible to realize major peace dividends, much larger than we have so far achieved since the end of the Cold War. With those liberated resources and energies, it should then be possible to mount serious attacks on the real enemies of humanity—poverty, disease, ignorance, and environmental degradation.

You may believe that I've presented an outrageously optimistic picture of the future of arms control and international security. Perhaps I have. But my optimism is driven in part by a bleak, almost desperate pessimism about the human future if our energies do not shift away from defenses against what are often illusory enemies—other human beings—to what I just called our real enemies. One of the unintended consequences of strengthening the BWC regime may be that the world will be better equipped to deal with the biological warfare that nature directs at us, whether in the form of small disasters like Dutch elm disease or much larger ones like AIDS. Building that capability into the future BWC verification regime strikes me as a challenge to which all of you can help respond.



## Appendix B: List of Workshop Participants

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## Appendix C: Glossary

ACDA	U.S. Arms Control and Disarmament Agency
BL-4	Biosafety Level 4 (high-containment laboratory)
BW	biological weapon(s)
BWC	Biological and Toxin Weapons Convention/Biological Weapons Convention
CBW	chemical and biological weapons
CDC	U.S. Centers for Disease Control and Prevention
CPI	confidential proprietary information
CTBT	Comprehensive Test Ban Treaty
CW	chemical weapons
CWC	Chemical Weapons Convention
DNA	deoxyribonucleic acid
DOE	U.S. Department of Energy
FDA	U.S. Food and Drug Administration
FOIA	Freedom of Information Act
IAEA	International Atomic Energy Agency
IgG, IgA	immunoglobulin antibody types
NAM	Non-Aligned Movement
NATO	North Atlantic Treaty Organization
NSDM	National Security Decision Memorandum
PCR	polymerase chain reaction
ProMED	Program on Monitoring Emerging Diseases
R&D	research and development
UK	United Kingdom
UNSCOM	United Nations Special Commission
WHO	World Health Organization

